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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

S. Little
3-2-00

Docket No. 11770US03

In the Reissue Application of:

AINSWORTH et al.

Serial No. 09/143,503

Filed: August 28, 1998

Patent No. 5,554,121

Issued: September 10, 1996

For: INTRALUMINAL CATHETER WITH
HIGH STRENGTH PROXIMAL
SHAFT



Examiner: John D. Yasko, Jr.

Group Art Unit: 3763

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, BOX REISSUE, Washington, D.C. 20231 on February 22, 2000.

By: *George Wheeler*
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**RESPONSE ACCOMPANYING
SUPPLEMENTAL REISSUE DECLARATION**

Assistant Commissioner for Patents
Washington, D.C. 20231
Box Reissue

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This paper responds to the Office action dated February 9, 2000 requiring a Supplemental Oath. The Supplemental Oath signed by the inventors is attached.

The purpose of this paper is to demonstrate that the new, broader claim 18 submitted in the present reissue application is not prohibited by the reissue recapture rule. The recapture rule only applies to claim limitations relied upon during original prosecution to avoid the prior art, and later removed during reissue. The applicants never relied on the balloon limitation in their claims during original prosecution as a basis to avoid any prior art. All the prior art applied by the



Examiner during original prosecution disclosed a dilatation balloon, so this feature did not avoid, and was not argued to avoid, the prior art.

Section 1412.02 of the MPEP states: "A reissue will not be granted to 'recapture' claimed subject matter deliberately canceled in an application to obtain a patent. *In re Clement*, 131 F.3d 1464, 45 USPQ2d 1161 (Fed. Cir. 1997) [other citations omitted]." The MPEP then goes on to expressly rely on *In re Clement* regarding the requirements of the recapture rule.

In re Clement indicates that the recapture rule does not apply unless the subject matter added during reissue was given up during original prosecution to avoid the prior art.

The first step in applying the recapture rule is to determine whether and in what "aspect" the reissue claims are broader than the patent claims. *** The second step is to determine whether the broader aspects of the reissue claims relate to surrendered subject matter. To determine whether an applicant surrendered particular subject matter, we look to the prosecution history for arguments and changes to the claims made in an effort to overcome a prior art rejection."

Clement, 45 USPQ2d at ____ (emphasis added).

The following error is recited in the accompanying supplemental reissue declaration as a basis for reissue. Claim 1 of U.S. Patent No. 5,554,121 as originally issued requires as one element a dilatation balloon, while the specification of the patent does not require a dilatation balloon in the invention as most broadly stated. The applicants thus state that the patentee originally claimed less than it was entitled to claim. This error is being corrected by submitting claims 18-23 and 26-56, which are not limited to a catheter having a balloon.

Claims 1-4 presented in the original application, U.S. Ser. No. 08/280,210, did not require a dilatation balloon. Specifically, claim 1 as originally presented recited:

1. An intraluminal catheter having a shaft formed of an extruded engineering thermoplastic polymer having a tensile strength greater than about 10,000 psi, an elongation greater than about 50% and a tensile modulus greater than about 300,000 psi.

Claims 5-10 in the application as originally filed did recite a balloon dilatation catheter.

In the first Office action, mailed May 11, 1995 (Paper No. 4), the Examiner rejected every claim in the application in view of Hamlin (U.S. Pat. No. 5,270,086, entitled "Multilayer Extrusion of Angioplasty Balloons"), in some cases combined with Burns (U.S. Pat. No. 5,259,839, entitled "Balloon Catheter with Guidewire Valve." Both Hamlin and Burns disclose balloon catheters.

In Paper No. 5, filed August 24, 1995, the applicants cancelled claim 1 and others, while retaining claims directed to a catheter including a dilatation balloon. No balloon limitation was added to any claim during prosecution. The applicants argued, in relevant part:

[T]he applicants believe that the teaching of Hamlin alone falls short of meeting all of the requirements of claim 5 as required by § 102(e). More particularly, Hamlin fails to disclose a proximal shaft portion formed of the prescribed polymeric material. Hamlin is directed to making a balloon of composite material for a dilatation catheter which is on the distal portion of the catheter shaft. The claims of the present invention require the proximal catheter shaft portion to be formed of a prescribed polymeric material having certain mechanical properties, whereas, Hamlin teaches forming the balloon of a polymeric material

which is disposed on the distal shaft portion. Moreover, there is no indication in Hamlin whether the polymeric material described therein has the requisite mechanical properties of the present invention.

Paper No. 5 at page 4; (emphasis modified). The applicants thus acknowledged that the prior art applied against their claims disclosed a balloon catheter.

In the next paper, the Examiner entered a new rejection based on Cornelius et al. (U.S. Patent No. 5,423,754) in view of Hamlin. Regarding Cornelius, the Examiner noted: "There is a balloon, 14, attached to the distal member and in communication with the lumen formed by the catheter." Cornelius indeed discloses a balloon dilatation catheter. For example, the Abstract of Cornelius begins as follows: "An over-the-wire angioplasty balloon catheter having a balloon bonded at its proximal and distal ends to an outer tubular member...."

The applicants did not argue respecting the Cornelius reference, and confined their remarks to distinguishing Hamlin. See Paper Nos. 7 and 8. A Notice of Allowance immediately followed, which made no further pertinent remarks. See Paper No. 9.

This prosecution history illustrates that each item of prior art applied by the Examiner recited a balloon catheter, and the applicant did not argue otherwise. A dilatation balloon limitation:

- was not added to any claims,
- was never argued to avoid the prior art of record, and
- had no value to distinguish any prior art applied in a rejection.

Therefore, by submitting claims that do not recite dilatation balloons, the applicants are not seeking to recapture subject matter they conceded originally to avoid the prior art and obtain a patent.

Finally, the applicants note that the Examiner telephoned the undersigned on January 19, 2000 to request a supplemental declaration. The accompanying declaration is submitted to comply with the Examiner's request.

Therefore, the applicants believe that all outstanding requirements have been met. The Examiner is requested to allow the present application to reissue on the present record.

Respectfully submitted,

February 22, 2000
DATE

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